



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,941	11/28/2000	Gustave Bergnes	CYTOP009C6	9330

22434 7590 07/26/2002

BEYER WEAVER & THOMAS LLP
P.O. BOX 778
BERKELEY, CA 94704-0778

EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 07/26/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,941

Applicant(s)

BERGNES ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

This application is a continuation of application 09/699,047. Claims 1-59 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 5, 19, and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Said claims recite the limitation "stereogenic center" in the claimed compounds, which is not recited in the main claims. Thus, there is insufficient antecedent basis for this limitation in the claims.
2. Claim 57 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. Note, claim 57 refers to Figure 3 which is a table of compounds, and thus, it is unclear as to which compounds are claimed.
3. Claims 58 and 59 are substantial duplicates of each other since both recite "a method of screening..." Said claims only differ in the preambles. However, the preamble of "KSP kinesin modulators" in claim 58 has the same meaning as the one of "compounds that bind to KSP kinesin" in claim 59.

Art Unit: 1624

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 31, 32, 45, 49-55, and 57 are rejected under 35 U.S.C. 102(a) as being anticipated by **Chenard et. al.** (EP 884,310). On pages 19-21 (Examples 5, 8, 10, 12, etc.), Chenard et. al. disclose quinazolinone compounds that are embraced by the claimed quinazolinone formula with $-NHR_4$, or $-N(CH_2)R_3R_4$.

5. Said claims are also anticipated by **Spirkova et. al.** (CA 132:35672 – CAS printout), see the compound of *4(1H)-Quinazolinone, 2-[(dimethylamino)methyl]-* (RN 252570-57-3).

6. Claims 31-45, and 57 are rejected under 35 U.S.C. 102(a) as being anticipated by **Debnath et. al.** (J. Med. Chem., 1999, 42, 3203-3209 – cited on IDS). On page 3205, Debnath discloses compounds labeled as ADS-J11, ADS-J12, ADS-J13, ADS-J14, and ADS-J16, which are embraced by the instant claims when the quinazolinone is substituted with $-N(R_4)(C=O)R_3$.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1624

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 31-55, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by the following references:

- a. **Padia** (US 5,756,502): See Examples C, D, K, 1-4, 7, 8, etc.
- b. **Bellina et. al.** (WO 98/26664) : See compounds 18, 19, 81, and 127.
- c. **Pandey et. al.** (CA 124:331723 – CAS printout): See the compound of *Benzamide, N-[[3-(4-acetylphenyl)-3,4-dihydro-4-oxo-2-quinazolinyl]methyl]-* (RN 176772-15-9).
- d. **Parasharya et. al.** (CA 121: 134062 – CAS printout): See the compound of *4(3H)-Quinazolinone, 3-(4-hydroxyphenyl)-2-[(phenylamino)methyl]-* (RN 156672-31-0).
- e. **Saari et. al.** (CA 117: 191731): See the compound of *4(1H)-Quinazolinone, 2-[[5-ethyl-1,2-dihydro-6-mehtyl-2-oxo-3-pyridinyl]amino]methyl]-* (RN 143707-89-5).
- f. **Farghaly et. al.** (CA 114:122242 – CAS printout): See the compound of *4(3H)-Quinazolinone, 3-(4-chlorophenyl)-2-[[2,3-dihydro-1,5-dimethyl-3-oxo-2-phenyl-1H-pyrazol-4-yl]amino]methyl]-* (RN 132111-60-5).
- g. **El-Nasser Ossman et. al.** (CA 106: 207516 – CAS printout): See the compound of *Benzenesulfonamide, 4-[[3,4-dihydro-4-oxo-3-phenyl-2-quinazolinyl)methyl]amino]-* (RN 108282-55-9).

- h. **Rao et. al.** (CA 105: 97416 – CAS printout) : See the compound of 4(3H)-*Quinazolinone, 6,8-dibromo-2-[(dimethylamino)methyl]-3-(4-methylphenyl)-* (RN 103952-94-9).
- i. **Kumar et. al.** (CA 102: 142800 – CAS printout) : See the compound of 4(3H)-*Quinazolinone, 3-phenyl-2-[[2-(phenylethyl)amino] methyl]-* (RN 19062-63-6).
- j. **Chaurasia et. al.** (CA 96: 6681 – CAS printout) : See the compound of 4(3H)-*Quinazolinone, 3-(2-benzothiazolyl)-2-[2-(diethylamino) ethyl]-monohydrochloride* (RN 80144-66-7).
- k. **Tani et. al.** (CA 93 :26374 – CAS printout) : See the compound of 4(3H)-*Quinazolinone, 6-amino-2-[(diethylamino) methyl]-3-(2-methylphenyl)-* (RN 73832-37-8).
- l. **Ager et. al.** (CA 86: 83505 – CAS printout) : See the compound of 4(3H)-*Quinazolinone, 2-[[1,1-dimethylethyl)amino] methyl]-3-(2-methylphenyl)-monohydrochloride* (RN 61555-09-7).
- m. **Gupta et. al.** (CA 69: 42637 – CAS printout) : See the compound of 4(3H)-*Quinazolinone, 2-(2-hydrazinoethyl)-3-phenyl-* (RN 15647-65-1).
- n. **Singh et. al.** (CA 92: 58712 – CAS printout) : See the compound of 4(3)-*Quinazolinone, 3-[3-[[bis (2-chloroethyl)amino] methyl]-4-hydroxyphenyl]-2-[[bis(2-hydroxyethyl)amino] methyl]-* (RN 72544-40-2).

Art Unit: 1624

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 31, 32, 45, 49-55, and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by **Chenard et. al.** (US 6,136,812). See column 28, compound on lines 31-51.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

9. Claims 31-57 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The list of purchased compounds indicates that applicant did not invent

Art Unit: 1624

the claimed compounds. Even though R-configuration is recited in some claims, such a configuration is still embraced in the racemic mixtures of the purchased compounds, and can be separated by conventional method known in the art. Therefore, the claimed compounds are not novel even when their R-isomers are claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Padia** (US'502) in view of **Bisset et. al.** (5,561,133). Claims 1-30 are drawn to method of treating cellular proliferative diseases, and treating disorders associated with KSP kinesin activity using compounds of substituted quinazolinones.

Padia teaches compounds of quinazolinones as claimed herein (see 102 rejection above). However, Padia applies said compounds in suppressing appetite, and reducing gastric acid secretion. Such a difference can be remedied by the teaching of Bisset et. al. (US'133).

Bisset et. al. teach a genus of quinazolinone compounds that can treat cancer – a disorder of cellular proliferation. Said compounds inhibit DNA synthesis, and thus halt mitotic process.

Art Unit: 1624

Although Bisset et. al. had been silent to the effect on kinesin, it would have been within the level of one skilled in the art to recognize such an effect from the teaching of Bisset et. al.

11. Thus at the time of the invention, it would have been obvious to arrive at the methods of treatment claimed herein in view of the combined teachings above.

Double Patenting

The **nonstatutory** double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 31-45, 56, and 57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-44, 57, and 60-71 of copending Application No. 09/ 699,047. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds claimed in copending application (09/699,047) are embraced by those claimed herein.

13. Claims 31-45, 56, and 57 are also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31, 32, 34-45,

Art Unit: 1624

and 56 of copending Application No. 09/724,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of compounds claimed in copending application (09/724,712) overlaps with the scope claimed herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:00-5:30).

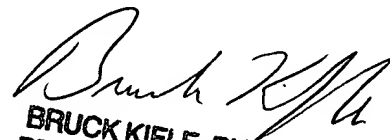
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Mukund Shah
Supervisory Patent Examiner
Art Unit 1624

T. Truong

July 22, 2002


BRUCK KIFLE, PH.D.
PRIMARY EXAMINER